NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Philippines **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Food and Drug Administration DEPARTMENT OF HEALTH**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** MARIA CECILIA C. MATIENZO Director IV Center for Device Regulation, Radiation Health, and Research Food and Drug Administration DEPARTMENT OF HEALTH Contact: (02) 8815-9600 Email: cdrrhr@fda.gov.ph; cdrrhr.rrd@fda.gov.ph; [www.fda.gov.ph](http://www.fda.gov.ph) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other** **[X]:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Machines for the reception, conversion and transmission or regeneration of voice, images or other data, incl. switching and routing apparatus (excl. telephone sets, telephones for cellular networks or for other wireless networks) (HS 851762); Transmission apparatus for radio-broadcasting or television, whether or not incorporating reception apparatus or sound recording or reproducing apparatus; television cameras, digital cameras and video camera recorders (HS 8525); Computer tomography apparatus (HS 902212); Apparatus based on the use of X-rays for dental uses (HS 902213); Apparatus based on the use of X-rays, for medical, surgical or veterinary uses (excl. for dental purposes and computer tomography apparatus) (HS 902214); Radiation protection (ICS 13.280) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Updated Guidelines for Payment of Applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD), repealing FDA Circular No. 2018-004, (4 page(s), in English) |
| **6.** | **Description of content:** The proposed issuance aims to outline, harmonize, and consolidate the updated guidelines for payment of applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD), repealing FDA Circular No. 2018-004. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Provide updated clarificatory guidelines for the payment of applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD).; Other |
| **8.** | **Relevant documents:** * FDA Circular 2018-004: "Guidelines for Payment of Applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD)"
* DOH Administrative Order (AO) No. 2020-0035: "Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other related Authorizations"
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| **9.** | **Proposed date of adoption:** 4th quarter of 2021 **Proposed date of entry into force:** 15 days after publication  |
| **10.** | **Final date for comments:** 30 days from notification |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** MR. NEIL P. CATAJAY Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati CityPhilippines 1200 (632) 7751 4700; (632) 7751 4706 Email: bps@dti.gov.ph <http://www.bps.dti.gov.ph> |